



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/594,485

09/27/2006

James Farina

1702 WO/US

1304

7590 08/27/2008
Christine Rebman Cooke
Mallinckrodt
675 McDonnell Boulevard
P O Box 5840
St Louis, MO 63134

EXAMINER

NIESZ, JASON KAROL

ART UNIT

PAPER NUMBER

3751

MAIL DATE

DELIVERY MODE

08/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,485	Applicant(s) FARINA, JAMES	
	Examiner JASON K. NIESZ	Art Unit 3751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-14, 16, 17, 19-24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14, 16, 17, 19-24, 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/17/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 10/17/2006 was considered by the examiner.

Claim Objections

2. Claim 19 objected to because of the following informalities: Claim 19 is recited as depending on claim 18, which has been cancelled. Appropriate correction is required. For the purpose of application of prior art claim 19 will be interpreted to depend on claim 16.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 6-13, 16, 17, 19-24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madaio (US Patent 3,853,157) in view of Baldwin (US Patent 4,863,429).

In Re claims 1 and 12 with reference to Figure 1 Madaio discloses an apparatus for storing and dispensing a material from a pressurized container comprising a pressurized container (6) having a dispensing valve (11), said dispensing valve having a stem with a distal end protruding from the pressurized container (11) and a proximal

Art Unit: 3751

end extending into the pressurized container (9). Madaio further discloses a syringe (46) and a removable adaptor (29).

Madaio doesn't disclose an on/off locking member.

With reference to Figure 1 Baldwin discloses a syringe having an on/off locking member (81) attached to the syringe through a luer lock (79).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Madaio apparatus by attaching the on/off locking member from Baldwin to the Madaio syringe, in order to allow more precise control of the filling operation.

In Re claim 2 with reference to Figure 1 Madaio discloses a reciprocating valve (11).

In Re claim 3 with reference to Figure 1 Madaio discloses a hollow valve stem (37) having a closed end (13) and a covered opening (36). With reference to Figure 5 Madaio discloses moving the valve stem into the pressurized container to uncover the opening.

In Re claim 4 Madaio in view of Baldwin as applied to claim 3 discloses all the limitations, but doesn't disclose a gasket covering the liquid opening. With reference to Figure 1 Madaio discloses a gasket surrounding the valve stem (23). One of ordinary skill in the dispensing art would know to use a gasket to protect fluid tight connections from leaking. Therefore, it would have been obvious to one of ordinary skill in the art to modify the Madaio apparatus by adding a ring gasket covering the liquid opening, in order to prevent liquid from leaking out of the dispensing apparatus.

In Re claim 6 with reference to Figure 1 Madaio discloses a bag (6) and pressurizing gas (2).

In Re claim 7 with reference to Figure 1, Madaio discloses a bag (6) and pressurizing gas (2). The examiner notes that the gasket applied to claim 4 above would necessarily be slidable to preserve the function of the valve.

In Re claims 8 and 9 with reference to Figure 1 Madaio discloses a valve connector (15) having a central opening (9) connected to the bag and the valve stem. Madaio further discloses a biasing spring (19) which biases the valve stem outwardly from the pressurized container.

In Re claim 10 with reference to Figure 1 Madaio discloses an adaptor (29) comprising two female sockets (the socket holding the valve stem: 11, and the socket holding the syringe: 43) connected by a material flow path passageway (41).

In Re claim 11 with reference to Figure 1 Madaio discloses an adaptor (29) comprising two female sockets (the socket holding the valve stem: 11, and the socket holding the syringe: 43) connected by a material flow path passageway (41).

In Re claim 13 with reference to Figure 1 Madaio discloses a reciprocatably (sic) actuated piston (51).

In Re claim 16 the apparatus applied to claim 1 above, during ordinary use and operation necessarily performs the method of claim 16 with the exception of activating the on/off member for permitting flow and activating the on/off member to isolate the material. Both of these steps are obvious applications of said on/off member and do not limit claim 15 beyond the scope of the prior art.

In Re claim 17 Madaio in view of Baldwin as applied to claim 16 above discloses all the limitations, but doesn't disclose the step of replacing the stem of the syringe with a needle, activating the on/off member to the on position, and expelling material from the syringe chamber to a closed system. The examiner notes that the step of replacing a syringe stem with a needle and dispensing it's contents into a closed system (a human body for example) are so obviously associated with a syringe as to be substantially inherent. Furthermore, the step of activating the on/off locking member to the on position is inherently required to dispense the material held in the syringe.

In Re claim 19 with reference to Figure 1 Madaio discloses a hollow valve stem (37) having a closed end (13) and a covered opening (36). With reference to Figure 5 Madaio discloses moving the valve stem into the pressurized container to uncover the opening.

In Re claim 20 Madaio in view of Baldwin as applied to claim 3 discloses all the limitations, but doesn't disclose a gasket covering the liquid opening. With reference to Figure 1 Madaio discloses a gasket surrounding the valve stem (23). One of ordinary skill in the dispensing art would know to use a gasket to protect fluid tight connections from leaking. Therefore, it would have been obvious to one of ordinary skill in the art to modify the Madaio apparatus by adding a ring gasket covering the liquid opening, in order to prevent liquid from leaking out of the dispensing apparatus.

In Re claim 21 with reference to Figure 1 Madaio discloses a bag (6) and pressurizing gas (2).

In Re claims 22 and 23 with reference to Figure 1 Madaio discloses a valve connector (15) having a central opening (9) connected to the bag and the valve stem. Madaio further discloses a biasing spring (19) which biases the valve stem outwardly from the pressurized container.

In Re claim 24 with reference to Figure 1 Madaio discloses an adaptor (29) comprising two female sockets (the socket holding the valve stem: 11, and the socket holding the syringe: 43) connected by a material flow path passageway (41).

In Re claim 26 the examiner notes that it would have been an obvious matter of design choice to use the Madaio in view of Baldwin apparatus to dispense any material desired by the applicant.

In Re claim 27 Madaio in view of Baldwin as applied to claim 16 above disclose all the limitations but doesn't disclose the step of replacing the syringe stem with a needle, activating the locking member to the on position, or expelling material from the syringe chamber to a closed reactor or vessel. It is commonly known in the art to modify a syringe by replacing its stem member with a needle and using said needle to dispense the material in the syringe into a vessel. Furthermore, the examiner notes that the method applied to claim 16 concludes by activating the on/off member to the off position as required by claim 27, and that the step of activating said on/off member to the on position is inherently required by any dispensing operation. Therefore, it would have been obvious to one of ordinary skill in the art to replace the syringe stem of the Madaio in view of Baldwin apparatus with a needle, activate the on/off member to the on

position, and dispense the contents of the syringe into a vessel, in order to make use of the material dispensed into the syringe.

In Re claim 28 with reference to Figure 1 the use of the reciprocable (sic) syringe piston (51) to expel the contents of the syringe is inherent in the function of the Madaio apparatus.

5. Claims 14 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madaio in view of Baldwin in further view of Cullen (US Patent 3,371,825).

In Re claim 14 Madaio in view of Baldwin as applied to claim 6 above discloses all the limitations, but doesn't disclose desiccant.

Cullen discloses a dispenser comprising a pressurized gas mixed with a drying agent (Column 4, lines 13-16), which acts to remove water to prevent the breakdown of the propellant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Madaio apparatus by adding a desiccant to the propellant gas, for the motivation disclosed above of preventing the breakdown of the propellant, as well as for preventing corrosion of the container.

In Re claim 29 Madaio in view of Baldwin as applied to claim 19 above discloses all the limitations, but doesn't disclose desiccant.

Cullen discloses a dispenser comprising a pressurized gas mixed with a drying agent (Column 4, lines 13-16), which acts to remove water to prevent the breakdown of the propellant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Madaio apparatus by adding a desiccant

Art Unit: 3751

to the propellant gas, for the motivation disclosed above of preventing the breakdown of the propellant, as well as for preventing corrosion of the container.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tsutsui et al (US Patent 6,510,968 B2) discloses a pressurized dispenser functioning substantially similarly to the applicant's dispenser, and having a ring gasket sealing the inlet port. Brony (US Patent 5,620,434) discloses a link for filling needle less syringes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON K. NIESZ whose telephone number is (571)270-3920. The examiner can normally be reached on mon-fri 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Huson can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3751

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory L. Huson/
Supervisory Patent Examiner, Art Unit 3751

Jason K Niesz
Examiner
Art Unit 3751
